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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,034	12/04/2000	Cheryl A. Pederson	56094US002	4710

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER	
KOPPIKAR, VIVEK D	

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
02/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	09/729,034	PEDERSON ET AL.	
	Examiner	Art Unit	
	VIVEK D. KOPPIKAR	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 12-37 have been examined in this application. This communication is a Final Office Action in response to the "Amendment" and "Remarks" filed on January 23, 2007.

Claim Objections

2. Claims 12-37 objected to because of the following informalities: It is not clear what is meant by the phrase: "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk or surgical site infection are selectable for a given health care facility." Specifically, it is not clear what items, either health care delivery practices or surgical procedures, are being selected by this limitation. For the purposes of examination, the Office will interpret this limitation as meaning that the health care delivery practices are selectable. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 12-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram et al., 'Guideline for prevention of surgical site infection" (hereinafter Guidelines) in view of Ormond-Walshe, Sarah, "Computerized databases in infection control" (hereinafter Walshe) and in further view of US Patent Number 6,157,853 to Blume and in even further view of US Patent

Number 5,562,448 to Mushabac and in even further view of US Patent Application Publication 2002/0077865 to Sullivan and in even further view of US Patent Number 6,509,730 to Afsah.

(A) As per claim 12-13, Guidelines discloses a method for managing the occurrence or risk of surgical site infection incident to a surgical procedure (Guidelines: pages 100-120), the method comprising:

(a) identifies a plurality of stages (mapping) of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage, and a postoperative stage (Guidelines: page 98);

(b) identifies one or more points-of-care within each identified stage of operative care associated with the surgical procedure (Guidelines: page 98);

(c) for each point-of-care associated with the surgical procedure, identifies one or a plurality of health care delivery practices associated with a surgical procedure sources of measurable risk of surgical site infection (Guidelines: page 98);

(d) for identified surgical site infection risks, identifying at least one practice for either or both managing or reducing the risks, either individually for each risk or collectively for more than one risk (Guidelines: pages 106-116)

Guidelines do not explicitly disclose that the identified practice or practices associated with the surgical procedure within each point-of-care to provide a set of sequential practices throughout each of the stages of operative care (pages 100-120)

Guidelines does not explicitly disclose

Aligning the practices in a manner that provides a desired management of the overall occurrence or risk of surgical site infection. However, Walshe discloses aligning the practices in

a manner that provides a desired management (monitoring) of the overall occurrence or risk of surgical site infection (i.e. establishment of surveillance and control programs was strongly associated with reductions …)(page 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of reducing infection rates (page 3).

Guidelines and Walshe does not explicitly disclose that for each of the compliance indicators, generating a flag when a given health care practice is not in compliance with a rule to align the health care practices to the rule, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

The above mentioned references do not teach the following feature which is taught by Sullivan (Section [0055]):

wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk or surgical site infection are selectable for a given health care facility.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]).

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11).

(B) As per claims 14-21, these claims are substantially similar in scope to claims 12-13 and are rejected on the same basis. The limitations claimed in these claims are taught in Guidelines(Pages 100-120).

(C) As per claim 22, Guidelines discloses a method for managing risks for surgical site infections incident to a surgical procedure, the method comprising:

evaluating a practice associated with the surgical procedure that poses an infection risk during a stage or the surgical procedure (Guidelines: Page 106-116);

Guidelines does not disclose storing data indicative of the practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedures, however, this feature is taught by Walshe (Walshe: Page 3, Paragraph 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of developing an enhanced means of reducing infection rates (page 3).

Guidelines in view of Walshe does not teach a step of identifying via a compliance indicator when the data indicative of the practice associated with a procedure is not in compliance with a rule established for the practice, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a

surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]).

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11).

(D) As per claim 23, in the combined method of Guidelines in view of Walshe and Jacober the step of identifying when the data indicative of the practice is not in compliance with the rule comprises generating a flag for the data (Jacober: Claims 32 and 35). The motivation for making this modification to the method of guidelines is the same as set forth above in the rejection of claim 22.

(E) As per claims 24-25, in the combined method of Guidelines in view of Walshe and Jacober further comprises a step of prompting medical personnel to take further action when the flag is generated (Jacober: Claims 32-35) and the flag is cleared when the further action is taken

(Jacober: Claim 34). The motivation for making this modification to the method of guidelines is the same as set forth above in the rejection of claim 22. (Note: In Jacober the medical personnel takes further action by sliding the tray of the medication dispenser to remove the medication (Claim 32)).

(F) As per claims 26-37, these claims repeat features previously addressed in the rejection of claims 12-25 and are rejected on the same basis.

Response to Arguments

5. Applicant's arguments, filed on June 5, 2007, with respect to the pending claims have been considered but are moot in view of the new grounds of rejection.

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Conclusion

6. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

2/9/2008

/Joseph Thomas/

Supervisory Patent Examiner, Art Unit 3626